

### REMARKS

#### **Pending Claims**

Claims 1-15 and 33-57 are all the claims pending in the application.

#### **Claim Objections**

Claims 39-43 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Applicant traverses the objection.

The Examiner cites col. 1, lines 20-40 of Alfano (U.S. Patent No. 5,467,767) as providing evidence that the claims recite a natural response to light. However, the cited does not mention anything about relative fluorescence of exposed or reflected light. The section cited describes relative fluorescence of non-cancerous and cancerous tissue.<sup>1</sup> Therefore, the cited art is not relevant to the rejection.

Furthermore, the Examiner alleges "it is the natural response of living body tissues exposed to excitation light to have greater fluorescence than the reflected reference light" (Office Action, page 2). However, if this were the case, then claims 40, and 42 would be immediately allowable because they recite the exact opposite of what the Examiner has alleged to be a natural response. The Examiner has improperly rejected all of claims 39-43. Therefore, claims 39-43 should be patentable.

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<sup>1</sup> "By determining the wavelengths at which maximum intensities are attained for the tissue in question and by comparing these peak wavelengths, either visually or electronically, to the peak wavelengths derived from a known non-cancerous tissue, or by comparing the spectrum of the excited tissue with the spectrum of a known noncancerous tissue one can determine the carcinomatoid status of the tissue in question. The invention is based on the discovery that the visible luminescence spectra for cancerous and non-cancerous tissue are substantially different and that the differences are such that visible luminescence from tissue can be used to detect the presence of cancer. " (col. 1, lines 29-40).

Similarly, the Examiner's contention that claims 39-43 are natural results of excitation are completely without merit with reference to the art of record. For example, Palcic specifically teaches that a result of excitation light provides a light output received over a reference light output. See col. 5 lines 16-22 and col. 6, lines 44-48.

**Claim Rejections - 35 U.S.C. § 101**

Claims 39-43 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The Applicant traverses the rejection.

This rejection is respectfully requested to be removed for at least the reasons stated above for claims 39-43 being in proper dependent form.

**Claim Rejections - 35 U.S.C. § 103**

Claims 1-15 and 33-47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Palcic et al. (US 5,827,190) in view of Richards-Kortum et al. (US 5,421,337). The Applicant traverses the rejection.

Claim 33 recites, *inter alia*, the method of displaying a tissue state image of claim 1:

“wherein the operation processing includes:

dividing values of the first fluorescence image by values of the second fluorescence image to obtain chrominance signal components; and

transforming values of the reflected reference light image into a luminance signal component.”

The Examiner concedes the Palcic does not specifically mention chrominance or luminance signal components with respect to the fluorescence image and reflected reference light or judgment means based on a ratio (Office Action, page 5). Furthermore, the Examiner alleges Richards-Kortum makes reference to correlation features of fluorescence spectra to tissue type in a quantitative way using ratios of fluorescence intensities at various wavelengths from the fluorescent image and reflected light (Office Action, page 5).

As stated in the previous Amendment, the teachings of Palcic teach away from the teachings of Richards-Kortum, and as such the Examiner may not rely on the combination of teachings of Palcic and Richards-Kortum to teach anything. The Examiner has not offered any rebuttal on this point. The references are clearly directed to different light reactions of tissue, for differing wavelengths. There is no justification for the combination, except as a matter of hindsight reconstruction. The disparate teachings would not aid diagnosis, but rather confuse the diagnosis since each reference is seeking minima and maxima for completely opposite purposes. Therefore, the proffered motivation is without support. Palcic teaches an endoscope having an integrated CCD sensor where the intensity of a disease area will be reduced and normal tissue's intensity will be increased.<sup>2</sup> Richards-Kortum teaches a method and apparatus of spectral diagnosis of diseased tissue. Richards-Kortum specifically teaches a florescence intensity of normal tissue is greater than adenomas (diseased tissue) in the 400-420 nm range, but lower in the 430-480 nm range.<sup>3</sup> Because Richards-Kortum discloses both higher and lower intensities for adenomas and Palcic discloses only lower intensities for diseased tissues Palcic teaches away from the teachings in Richards-Kortum. Therefore, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings.

The Examiner is improperly relying on the combined teachings of Palcic and Richards-Kortum to disclose the dividing values of the first fluorescence image by values of the second fluorescence image to obtain chrominance signal components feature of claim 33. The Examiner alleges again the "Response to Arguments" section of Office Action that the rejection is upheld

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<sup>2</sup> "If diseased tissue is present, the intensity of the green autofluorescence image will be reduced over the diseased area while the remittance light image will be substantially unaffected. If tissue is normal, the intensity of the green autofluorescence image will be increased relative to the diseased tissue and the remittance light image will continue to be substantially unaffected." (Palcic, col. 6, lines 44-51).

<sup>3</sup> "The downward sloping region from 400-420 nm reflects the blue region of the spectrum in which the relative fluorescence intensity of the adenomas is relatively greater than that of normal tissues. The flat region from 430-480 nm represents peak at 460 nm, where the fluorescence intensity of normal tissue is greater than that of adenomatous tissue." (Richards-Kortum, col. 13, lines 6-11).

because the Richards-Kortum discloses higher and lower intensities for adenomas and that the rejection is maintained nonetheless (Office Action, page 2). Even, if Richards-Kortum discloses higher and lower intensities, the teachings of Palcic teach away from the teachings of Richards-Kortum, and as such the rejection should be removed. Therefore, claim 33 should be patentable. Claims 34-35 depend from claim 33 and should be patentable for at least the same reasons as claim 33. To the extent Richards-Kortum is cited to teach wavelength properties for different layers, the reference does not further teach processing of first and second florescence values or referring to a normalized value to a look up table (claim 34) or reference of normalized value to a look up table generally (claims 35, 37-38).

The Examiner relies on the combination of the teachings of Palcic and Richards-Kortum for the 35 U.S.C. § 103 rejection of claims 36-47 and therefore those claims should be patentable as well for at least the above stated reasons.

The Examiner rejects alleges newly added claims 48-57 unpatentable because they either add new matter or because of the teachings of Richards-Kortum.<sup>4</sup> The claims do not add new matter because the ranges are fully support in the Specification. For example, the “greater than 480” limitation of claims 52, and 53 are disclosed in paragraph [0008].<sup>5</sup> The “below 430 nm” limitation in claims 54 and 55 are supported in paragraph [0190].<sup>6</sup> The “greater than 640 nm”

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<sup>4</sup> It should be noted the Examiner does not specify 35 U.S.C. § 102 or 35 U.S.C. § 103 as the basis for the rejection (Office Action, page 3).

<sup>5</sup> “The normalized fluorescence intensity described above is an index utilized for discriminating the normal tissues and the diseased tissues of the living body from each other in accordance with characteristics such that a spectral pattern of the fluorescence, which is produced from the normal tissues of the living body when the normal tissues are exposed to the excitation light, and the spectral pattern of the fluorescence, which is produced from the diseased tissues of the living body when the diseased tissues are exposed to the excitation light, vary from each other at the wavelength region in the vicinity of 480 nm.” (Specification, paragraph [0008]).

<sup>6</sup> “The narrow-band fluorescence image is a second fluorescence image having been obtained by detecting fluorescence components of fluorescence having been produced from living body tissues exposed to excitation light, which fluorescence components have wavelengths falling within a specific wavelength region of 430 nm to 530 nm.” (Specification, paragraph [0190]).

mn" limitation of claims 56, and 57 are disclosed in paragraph [0176].<sup>2</sup> Therefore, the claims do not introduce new matter. The 35 U.S.C. § 112 support for the particular ranges lends the proper support for the general wavelength ranges.

Furthermore, in relying on Richards-Kortum to teach the ranges of claims 48-57, the Examiner is not applying the proper range anticipation rules under the M.P.E.P. In M.P.E.P. 2131.03 (II):

“claimed subject matter must be disclosed in the reference with ‘sufficient specificity to constitute an anticipation under the statute.’”

In *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) a court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. If, as in the *Atofina* case, even when the claimed ranges overlapped there was not sufficient specificity for anticipation, then when “greater than 680 nm” is disclosed (Richards-Kortum, col. 13, lines 12-14), this does not anticipate “greater than 480 nm” as recited in claims 52 and 53. In other words, mere comparison of ranges, whether they overlap, or whether they are specifically disclosed, is not enough for meet the M.P.E.P. standard of sufficient specificity. Therefore, claims 48-57 should be patentable.

Additionally, please note a “tissue state image” is obtained by calculations employing a first fluorescence image of a specific wavelength band, a second fluorescence image and a reflectance image. Whether the “tissue state image” is suited for diagnosis, that is, whether the light receiving range is normal or abnormal, is not judged based on the “tissue state image,” but rather judged based on the original images (the first fluorescence image of a specific wavelength band and the second fluorescence image, and the reflectance image) which are not displayed, but

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<sup>2</sup> “In this embodiment, in order for a fluorescence image to be obtained, the excitation light Le having a wavelength of 410 nm is irradiated to the living body tissues 1. Also, in order for a reflected reference light image to be obtained, the near infrared light having a wavelength of 780 nm is irradiated as the reference light Ln to the living body tissues 1.” (Specification, paragraph [0176]).

used in the aforementioned calculations. Thereafter, whether the "tissue state image" is suited for being diagnosed is displayed within the "tissue state image."

Also, a distinguishing feature of the present invention is that whether a normalized image (such as the "tissue state image") is suited for diagnosis is judged not utilizing the normalized image (the "tissue state image"), but utilizing image prior to normalization (the original images).

Even in the case that judgment regarding whether a "tissue state image" is suited for diagnosis cannot be performed utilizing the normalized image (the "tissue state image"), whether the "tissue state image" is suited for diagnosis can be judged accurately by utilizing images prior to normalization (the original images).

Palcic and Kortum are silent regarding these features, and therefore, the present application is patentable.

#### **Conclusion**


In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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